

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (withdrawn): A composition comprising gelatin and a pharmaceutically acceptable sulfite compound, the composition being suitable for preparation of a pharmaceutical capsule shell.

Claim 2 (withdrawn): The composition of Claim 1 wherein the sulfite compound is present in an amount effective to inhibit cross-linking of the gelatin and/or pellicle formation in a capsule shell prepared from the composition.

Claim 3 (withdrawn): The composition of Claim 1 wherein the sulfite compound is selected from the group consisting of sodium metabisulfite, sodium thiosulfate, and sodium bisulfite.

Claim 4 (withdrawn): The composition of Claim 1 wherein the sulfite compound is present in an amount of not more than about 10% of the composition on a dry weight basis.

Claim 5 (withdrawn): The composition of Claim 1 wherein the sulfite compound is present in an amount of not more than about 5% of the composition on a dry weight basis.

Claim 6 (withdrawn): The composition of Claim 1 wherein the sulfite compound is present in an amount of not more than about 2% of the composition on a dry weight basis.

Claim 7 (withdrawn): The composition of Claim 1 further comprising at least one excipient selected from the group consisting of decomposition inhibitors, opacifying agents, preservatives, and plasticizers.

Claim 8 (withdrawn): The composition of Claim 1 further comprising a plasticizer selected from the group consisting of polyhydroxy-alcohols, esters of polyhydroxy-alcohols, dialkylphthalates, lower alkyl citrates wherein the lower alkyl has 1 - 6 carbon atoms, glycols, polyglycols, ricinoleic acid and ricinoleic acid esters.

Claim 9 (withdrawn): The composition of Claim 1 further comprising a plasticizer selected from the group consisting of sorbitol, glycerols, propylene glycols, and polyethylene glycols.

Claim 10 (withdrawn): The composition of Claim 1 further comprising a preservative selected from the group consisting of methylparabens, propylparabens, butylparabens, sorbic acid, benzoic acid, editic acids, phenolic acids, sorbates, and propionates.

Claim 11 (withdrawn): The composition of Claim 1 further comprising titanium dioxide.

Claim 12 (withdrawn): The composition of Claim 1 further comprising sulfur dioxide.

Claim 13 (withdrawn): The composition of Claim 1 that is in a form of capsule shells.

Claim 14 (withdrawn): The composition of Claim 13 wherein each of said capsule shells defines a fill volume.

Claim 15 (withdrawn): The composition of Claim 13 wherein the capsule shells are soft gelatin capsule shells.

Claim 16 (withdrawn): The composition of Claim 14 wherein the fill volume has a capacity of about 0.1 ml to about 2 ml.

Claim 17 (withdrawn): The composition of Claim 16 wherein the fill volume has a capacity of not more than about 1 ml.

Claim 18 (withdrawn): The composition of Claim 14 wherein the capsule shells are suitable for oral delivery of a drug contained in the fill volume.

Claim 19 (currently amended): A pharmaceutical dosage form comprising a fill material sealed in capsule shells, wherein the capsule shells comprise a sulfite compound, and wherein said sulfite compound is present in an amount sufficient to inhibit gelatin cross-linking and/or pellicle formation in the capsule shells upon storage of the dosage form; wherein the fill material comprises celecoxib.

Claim 20 (original): The dosage form of Claim 19 wherein the fill material is liquid.

Claim 21 (original): The dosage form of Claim 20 wherein the fill material is self-emulsifying upon contact with gastric fluid.

Claim 22 (currently amended): The dosage form of Claim 19 wherein the fill material comprises an amine agent that comprises at least one pharmaceutically acceptable primary or secondary amine,

wherein the amine agent in the fill material is present in an amount not more than about 10% of the composition on a dry weight basis effective in combination with the amine agent in the capsule shell, to inhibit gelatin cross-linking and/or pellicle formation in the capsule shell upon storage of the dosage form.

Claim 23 (currently amended): The dosage form of Claim 19 wherein the fill material comprises a pharmaceutically acceptable sulfite compound, wherein the sum of the amount of the sulfite compound in the fill material and the sulfite compound in the capsule shell is not more than about 10% of the composition on a dry weight basis present in an amount effective in combination with the amine agent in the capsule shell to inhibit gelatin cross-linking and/or pellicle formation in the capsule shell upon storage of the dosage form.

Claims 24-29 (cancelled).

Claim 30 (currently amended): The dosage form of Claim 19 [24] wherein the fill material further comprises at least one substance that promotes cross-linking of gelatin when in contact therewith, said substance being the drug or an excipient substance, and said substance acting independently or in combination with one or more other substances to promote said cross-linking.

Claim 31 (original): The dosage form of Claim 30 comprising a first and a second of said capsule shells, said first and second capsule shells being substantially identical; wherein upon

- (a) testing a first capsule shell in a first *in vitro* dissolution assay;
- (b) storing a second capsule shell in a closed container maintained at 40 °C and 85% relative humidity for a period of four weeks and, after said storage;
- (c) testing the second sealed capsule shell in a second *in vitro* dissolution assay which is substantially identical to the first *in vitro* dissolution assay;

the amount of drug dissolved at 45 minutes in the second dissolution assay is within ± 15 percent of the amount of drug dissolved at 45 minutes in the first dissolution assay, and wherein the first *in vitro* dissolution assay is conducted within a reasonably short time after preparation of the composition.

Claim 32 (original): The dosage form of Claim 19 further comprising (a) at least one excipient selected from the group consisting of decomposition inhibitors, opacifying agents, and preservatives; and (b) a plasticizer selected from the group consisting of sorbitol, glycerols, propylene glycols, and polyethylene glycols;

wherein the sulfite compound is selected from the group consisting of sodium metabisulfite, sodium thiosulfate, and sodium bisulfite; and

wherein the sulfite compound is present in an amount of not more than about 10% of the composition on a dry weight basis.

Claim 33 (currently amended): The dosage form of Claim 32 wherein the ~~fill material further comprises~~ celecoxib is present in an amount of about 10 to about 400 mg.